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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
08/692,314	08/05/96	HAMLIN R	21045-104

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EXAMINER	
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ART UNIT	**PAPER NUMBER**
1733	

DATE MAILED: 01/26/99

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)
08/692314	Hamlin
Examiner	**Group Art Unit**
Maki	1733

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

Period for Response

A SHORTENED STATUTORY PERIOD FOR RESPONSE IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a response be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for response specified above is less than thirty (30) days, a response within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for response is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication .
- Failure to respond within the set or extended period for response will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

☒ Responsive to communication(s) filed on 11-13-98.

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle,* 1935 C.D. 1 1; 453 O.G. 213.

Disposition of Claims

☒ Claim(s) 116, 118-125, 127, 128, 130-134, 136-143, 145-146, 148-165 is/are pending in the application.

Of the above claim(s)_____ is/are withdrawn from consideration.

☐ Claim(s)_____ is/are allowed.

☒ Claim(s) 116, 118-125, 127, 128, 130-134, 136-143, 145-146, 148-165 is/are rejected.

☐ Claim(s)_____ is/are objected to.

☐ Claim(s)_____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The proposed drawing correction, filed on_____ is ☐ approved ☐ disapproved.

☐ The drawing(s) filed on_____ is/are objected to by the Examiner.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119 (a)-(d)

☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 11 9(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number)_____.

☐ received in this national stage application from the International Bureau (PCT Rule 1 7.2(a)).

*Certified copies not received:_____.

Attachment(s)

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s)._____

☐ Interview Summary, PTO-413

☒ Notice of References Cited, PTO-892

☐ Notice of Informal Patent Application, PTO-152

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Other_____

Office Action Summary

1) The request filed on 11-13-98 for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) based on parent Application No. 08/692,314 is acceptable and a CPA has been established. An action on the CPA follows.

2) The disclosure is objected to because of the following informalities: the continuing data is described in four separate insertions:

- the insertion filed 11-13-98,
- the insertion filed 8-5-96,
- the insertion field 3-31-95, and
- the insertion filed 8-10-93.

Furthermore, (1) the insertion filed 11-13-98 has not been entered since its describes this application as being a "Continued Prosecution Application" ("A request for an application under this paragraph is the specific reference required by 35 U.S.C. 120 to every application assigned the application number identified in such request." 37 CFR 1.53(d)(7)) and (2) the insertion filed 8-5-96 describes this application as being a "continuation of copending application Serial No. 910458.CDP, filed March 31, 1995" instead of --continuation of copending application Serial No. 08/415,094, filed March 31, 1995--.

It is suggested to delete the insertion before the first line filed 8-5-96, 3-31-95 and 8-10-93, and to make a new insertion before the first line which states: --This application is a continuation of application serial no. 08/415,094, filed March 31, 1995, now abandoned; which is a continuation of application serial no. 08/105,353, filed August 10, 1993, now abandoned; which is a division of application serial no. 07/727,664, filed July 9, 1991, now U.S. Patent No. 5,270,086; which is a continuation-in-part of application serial no. 07/411,649, filed September 25, 1989 now abandoned.--

Appropriate correction is required.

3) Applicant is advised that should claims 137, 138 and 139 be found allowable, claims 153, 154 and 155 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Claims 137, 138 and 139 have the same scope as claims 153, 154 and 155 respectively.

4) The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5) Claim 150 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 150 is indefinite because it depends on itself. Should claim 150 depend on claim 136?

6) The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7) **Claims 116, 118-125, 127-128, 131-134, 136-143, 145-146 and 149-161 and 163-165 are rejected under 35 U.S.C. § 103 as being unpatentable over Levy (US Patent 4,490,421) in view of Japan '463 (JP 58-188463) and/or Dyke (US Patent 4,003,382) and further in view of "Coextruded composite film" by Parker, Patel (US Patent 4,335,723), Vaillancourt et al (US Patent 3,861,396).**

Levy, directed to a balloon for a catheter, discloses extruding a tube of polyethylene terephthalate, heating the tube and drawing the tube and inflating the tube to form a biaxially oriented balloon having a burst pressure of at least 200 psi (13.6 atm). At col 4 lines 45-50, Levy discloses fabricating the balloon catheter comprising the balloon by means of conventional techniques.

Japan '463, directed to a balloon for a catheter, shows a balloon secured at each end to a catheter tube wherein the balloon comprises two layers 13 and 14 with layer 14 being provided on layer 13. See abstract, figures. During an oral translation of Japan '463 by a PTO translator, the following information was obtained: Japan '463 discloses that layer 14 is a gas penetration layer which was formed by coating over a soft plastic film 13. Japan '463, which lists a variety of materials which can be used for layer 13, also teaches that layer 14 can be provided on the inside surface of layer 13. Also see translation provided by applicant.

Dyke, directed to a balloon catheter, discloses providing a balloon having an outer layer and an inner layer in the form of bands such that the bands can be activated with heat or solvent so that the balloon can be bonded to a catheter shaft.

Patel, directed to a balloon catheter, discloses coextruding two layers to form a tube which is to be used as the shaft of a catheter. Patel teaches using coextrusion so that the two layers are firmly connected to each other. The material of the outer layer is selected to be compatible with the balloon so that the catheter shaft and the balloon can be joined to each other by heat sealing or by adhesive.

Parker, directed to coextruded composite film, teaches bringing a first layer and second layer of polymers into contact in a single die while they are still in a molten state, extruding the layers from the die to form a tube and inflating the tube with air to stretch the tube to a desired thickness. Parker teaches bonding takes place inside the extruder die head and the film leaves the die as a completely multilayered structure. Parker et al teaches that by providing the second layer a "good sealing film" having the all the desired properties of the first layer can be obtained. Parker specifically discloses: "All coextruded films offer freedom from pinholes; it is virtually impossible for a pinhole in one film layer to line up with a pinhole which exits in another film." Parker lists "[a]dhesion to other substrates with or without adhesives" as being one of

the "property advantages offered by specially tailored coextruded composite films"

Vaillancourt et al, directed to the catheter art in general, discloses forming a tube (a drainage tube to be connected to a catheter) having two layers by using a conventional process such as spray coating, dip coating or coextrusion. See column 5 lines 1-5.

As to independent claims 116, 134 and 152 and dependent claims 133, 151, and 165, it would have been obvious to:

(i) coextrude two different polymeric materials so as to form a two layer tubing; and

(ii) use the two layer tubing in the Levy process which as noted above includes steps of heating the tube, drawing the tube and radially expanding the tube in a blow molding fixture to form the balloon such that the resulting balloon is sized and configured for intravascular coronary angioplasty use, has a burst pressure in excess of seven atmospheres, and the first balloon layer has a greater burst strength than the second balloon layer,

SINCE:

(a) Levy, directed to the balloon catheter art, teaches extruding plastic material to form a tubing which is to be used to form a balloon which has a burst pressure of at least 200 psi;

(b) Japan '463, directed to the balloon catheter art, teaches forming a two layer balloon of different materials FOR THE ADVANTAGE OF MAKING THE BALLOON MORE GAS IMPERMEABLE, and/or Dyke, directed to the balloon catheter art teaches forming a two layer balloon of different materials SO THAT THE INNER LAYER CAN BE USED TO BOND THE BALLOON TO THE CATHETER SHAFT; and

(c) it is conventional to use **coextrusion** to form two layer tubing as evidenced by Patel, Parker and Vaillancourt et al - Patel suggesting the use of **coextrusion** in the balloon catheter art FOR THE ADVANTAGE OF OBTAINING A FIRM CONNECTION BETWEEN THE TWO LAYERS, Parker suggesting the use of **coextrusion** of a low melting point plastic material with a high melting point plastic material IN ORDER TO FORM A TWO LAYER TUBE WHICH IS VIRTUALLY FREE FROM PINHOLES, and Vaillancourt et al suggesting the use of **coextrusion** as AN ALTERNATIVE TO OTHER TECHNIQUES SUCH AS SPRAY COATING A DIP COATING TO FORM A TWO LAYER COATING.

Hence, the prior art as a whole suggests/motivates forming a two layer balloon by the known technique of coextrusion (Patel, Parker and Vaillancourt) in order to improve the impermeabilty

(Japan '463) and/or adherabilty (Dyke) of a high burst pressure balloon formed by the process of Levy. Japan '463 and Dyke are applied in the alternative or in combination since (1) as to being applied in combination, each of Japan '463 and Dyke both suggest providing a balloon with two layers of different material and (2) as to being applied in the alternative, Japan '463 and Dyke provide different reasons for using a second layer - Japan '463 suggesting using a second layer to make the balloon more gas impermeable and Dyke suggesting using a second layer to improve bondablity of the balloon to a shaft.

Although no longer claimed, the following conclusion is made: It would have been obvious to one of ordinary skill in the art to attach the balloon to a catheter by using melt bonding since (a) Levy suggests fabricating a balloon catheter by a conventional technique which one of ordinary skill in the art would readily understand as including a step of attaching the balloon to a catheter, (b) Patel teaches attaching a balloon to a catheter tube by using an adhesive or by heat sealing and (c) Dyke which suggests attaching a balloon, which has an inner layer of a second material, to a catheter tube using melt bonding of the second material.

The limitation of the material of the outer layer and the material of the inner layer and the outer layer as set forth in claims 118-125, 127-128, 131-132, 136-143, 145-146, 149-150, 153-161, 163-164 would have been obvious in view of (a) the above noted suggestion from the secondary references to form a two layer balloon, (b) Levy's al's teaching that the biaxially oriented material of a layer of a balloon may be a polymer such as polyethylene terephthalate and (c) well known polymeric material for a layer of a balloon include polymeric material such as polyvinyl chloride, polyurethane and polyethylene as evidenced by Levy (column 1) and Patel (column 1). With respect to the inner layer being polyethylene, one of ordinary skill in the art would readily recognize from Parker that polyethylene would improve the heat sealability of the balloon. With respect to the claims directed to two different polyester materials, the use of two different polyester materials as set forth therein would have been obvious (a) the above noted suggestion from the secondary references to form a two layer balloon, (b) Levy's al's teaching that the biaxially oriented material of a layer of a balloon may be a polymer such as polyethylene terephthalate and (c) polyester having a relatively low crystallinity is taken as a well known heat sealable material per se in the bonding art.

8) **Claims 130, 148 and 162 are rejected under 35 U.S.C. § 103 as being unpatentable over Levy in view of Japan '463 and/or Dyke and further in view of Patel, Parker and Vaillancourt et al as applied above and further in view of Merrill and Lambert.**

Levy does not specifically recite coating the outer layer with a hydrophilic lubricous plastic.

Merrill teaches coating a balloon catheter with a hydrophilic material such as N-pyrrolidone.

Lambert teaches coating a catheter with a hydrophilic material such as polyvinylpyrrolidone. Lambert teaches that the hydrophilic coating has a much lower coefficient of friction when wet. Lambert teaches providing the hydrophilic coating on polymeric substrates such as polyesters.

As to claims 130, 148 and 162, it would have been obvious to coat the outer layer with a hydrophilic lubricous plastic so that advantageously the outer polymeric surface of the balloon catheter will have a low coefficient of friction when wet since (a) Levy teaches fabricating a catheter comprising the balloon and (b) Merrill and Lambert suggest coating a catheter with a hydrophilic plastic coating, which one of ordinary skill in the art would readily recognize becomes slippery when wet.

9) REMARKS

Applicant's arguments with respect to claims 116, 118-125, 127-128, 130-134, 136-143, 145, 146, 148-165 have been considered but are moot in view of the new ground(s) of rejection.

As noted in the office action dated 11-14-97, Wang et al US Patent 5,195,969 filed 4-26-91 is not available as prior art under 35 USC 102 against pending claims 116, 118-125, 127-128, 130-134, 136-143, 145-146, 148-165 since each of these claims is directed solely to subject matter disclosed in and entitled to the benefit of the filing date of 07/411,649 filed 9-25-89.

Applicant's argument that Levy does not teach or suggest a method of making a catheter balloon comprising co-extruding a tube having a first layer comprising a first polymeric material and a second layer comprising a second polymeric material which is different than the first polymeric material is not persuasive since the secondary art provides the suggestion / motivation to modify the process of Levy so as to use a co-extruded tube having a first layer comprising a first polymeric material and a second layer comprising a second polymeric material which is different than the first polymeric material to form the balloon INSTEAD OF using a single layer tube of one composition to form the balloon.

Applicant argues and the examiner agrees that Levy discloses a process for making a single layer balloon instead of a multi layer balloon. However, Japan '463 motivates one of ordinary skill in the art to modify the process of Levy so that a balloon having at least two layers is made instead of a single layer balloon for the advantage of preventing pinhole formation. Applicant fails to provide any reason or evidence why prevention of pinhole formation is not desired or needed by Levy. Applicant fails to cite any portion which shows that Levy desires pinhole formation and thereby rejects preventing pinhole formation. Examiner's position is that preventing pinhole formation is desirable in Levy because the process of Levy forms a balloon for a catheter which is to be inflated and Japan '463 teaches that a balloon for a catheter which has pinholes is considered by one of ordinary skill in the art to be "inferior".

Applicant argues and the examiner agrees that Japan '463 discloses using a coating process to form two layers instead of coextrusion. However, one of ordinary skill in the art would consider coextrusion and coating to be alternative techniques for forming two layers since Patel, Parker and Vaillancourt et al teach using coextrusion to form two layers. Use of coextrusion is not a novel technique for forming a tube having two layers.

See Parker et al. Use of coextrusion is not a novel technique in the balloon catheter art. See Patel. Furthermore, use of coextrusion is known to be an alternative to coating by spray coating or dip coating in the catheter art in general. See Vaillancourt et al. No unexpected results have been shown for using coextrusion instead of coating. Furthermore, Japan '463 attaches no importance to the use of coating to form the multi layer balloon since Japan '463 expressly states: "Any desired known procedure can be used as the method of forming the balloon part 5." (page 6 of translation).

Applicant's argument that Levy rejects certain polymers is not persuasive. FIRST: Instead of stating that he rejects certain polymers, Levy states: "Although PET homopolymer is the only polymer demonstrated herein, it is to be understood that any high molecular weight polymer that can be extruded into tubing and then drawn and expanded in general accordance with the aforesaid process is operable, for example, a PET copolyester or even a non-polyester, provided the resultant balloon exhibits the desired film properties, such as toughness, flexibility and tensile strength." SECOND: Levy fails to reject using a tube having two or more layers to form a balloon having two or more layers. THIRD: None of applicant's claims require the use of a

polymer for the first layer / first tube which is different than that disclosed and suggested by Levy.

Applicant's argument that Japan '463 teaches away from a relatively high pressure balloon is not persuasive since Japan and Levy are each directed to a balloon for a catheter.

With respect to applicant's arguments regarding Parker, the examiner makes the following comments: FIRST: Applicant's argument that Parker is limited to packaging is incorrect because Parker is directed to coextruded composite film. SECOND: Applicant's argument that Parker's teaching to collapse the film is useless and uncombinable with references relating to inflatable medical balloons is irrelevant since none of the claims require or exclude collapsing the balloon. THIRD AND MORE IMPORTANT: Applicant ignores Parkers' teaching that "All coextruded films offer freedom from pinholes; it is virtually impossible for a pinhole in one film layer to line up with a pinhole which exists in another film."

10) No claim is allowed.

11) Any inquiry concerning this communication or earlier communications from the examiner should be directed to Steven D. Maki whose telephone number is (703) 308-2068. The examiner can normally be reached on Monday to Friday from 8:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Ball, can be reached on (703) 308-2058. The fax phone number for Art Unit 1733 is (703) 305-7718. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0661.

STEVEN D. MAKI 1-18-99
PRIMARY EXAMINER
~~GROUP 1300~~
AU 1733

Steven D. Maki
January 18, 1999